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EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SCOTT SCHEWE, VICTOR SCHONELE, and JAN WEBER

Appeal 2009-003316
Application 10/617,428
Technology Center 1700

Decided: October 19, 2009

Before JEFFREY T. SMITH, BEVERLY A. FRANKLIN, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

ROBERTSON, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 23-25 and 43-45.[1] (Appeal Brief filed September 7, 2007, hereinafter "App. Br.," 2). We have jurisdiction pursuant to 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

THE INVENTION

Appellants describe a method of forming a polymeric tubing segment or parison for a medical device or medical device balloon. Claims 23 and 43, reproduced below, are representative of the subject matter on appeal.

> 23. A method of making a parison for forming a medical device balloon in which portions of the parison are slated to form cone and waist portions of the balloon and a portion is slated to form the balloon body, the method comprising a step of extruding polymeric material to form a tube, and forming the parison having said slated portions from the tube, wherein the extruding step is controlled to provide the extruded tube with a varying longitudinal orientation, such that the slated parison formed therefrom has variation providing a lower or higher orientation for the cone and waist slated portions of the parison relative to the portion slated to form the balloon body.
>
> 43. A method of forming a polymeric tubing segment for a medical device comprising extruding a tube of polymeric material through a die and cooling the extruded tubing by drawing it through a cooling region spaced at a gap length from the die to the cooling bath, wherein the drawing rate, or the gap length, or the cooling rate of the cooling region, or any combination thereof, is altered along the length of the segment,

[1] Claims 1-9, 13, 29, and 38-42 have been canceled. (Amendment After Final filed April 3, 2007). Claims 10-12, 14-22, 26-28, and 30-37 have been allowed. (Advisory Action mailed April 23, 2007).

whereby the segment is formed with at least two regions along the length thereof, a first of said regions and a second of said regions having different elongation at yield properties relative to each other and wherein

said alteration of the drawing rate, or the gap length, or the cooling rate of the cooling region, or combination thereof, is selected on the basis of the elongation at yield properties of said first and second regions.

THE REJECTIONS

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Pepin	US 5,614,136	Mar. 25, 1997
Chen	US 6,905,743 B1	Jun. 14, 2005

The Examiner separately rejected claims 23-25 and 43-45 under 35 U.S.C. § 102(b) as being anticipated by Pepin as evidenced by Chen.

ISSUES

Have Appellants shown that the Examiner reversibly erred in finding that Pepin discloses a method of making a parison as recited in claim 23?

Have Appellants shown that the Examiner reversibly erred in finding that Pepsin discloses the method of forming the polymeric tubing segment recited in claim 43?

Have Appellants shown that the Examiner reversibly erred in finding that the difference in elongation at yield value recited in claim 44 is inherent to Pepin's method?

FINDINGS OF FACT

The record supports the following findings of fact (FF) by a preponderance of the evidence.

1. The Examiner found that Pepin discloses the claimed process of forming a polymeric tube segment by extruding a polymeric tube, drawing/puling the tube through a cooling bath, and altering/varying the drawing rate to change dimensions in at least two regions or predetermined locations along the tube. (Examiner's Answer entered August 1, 2008, hereinafter "Ans.," 3-4).
2. The Examiner found that the changes in drawing/pulling rates of the polymeric material in Pepin:

> "inherently yield different orientations of the material within the article at the different locations. The examiner notes and submits that this different orientation inherently yields 'different stabilization' properties (e.g. elongation at yield properties) as is also evidenced by Chen et al. at col. 5, lines 35-40. Accordingly, the examiner submits that the choice to change the dimensions in Pepin et al. by adjusting the drawing/pulling rate, also changes the 'longitudinal stabilization' properties (e.g. elongation at yield properties) of the article in the same locations the dimensions are changed."

(Ans. 10-11).

3. Figure 3 of Appellants' Specification is reproduced below:

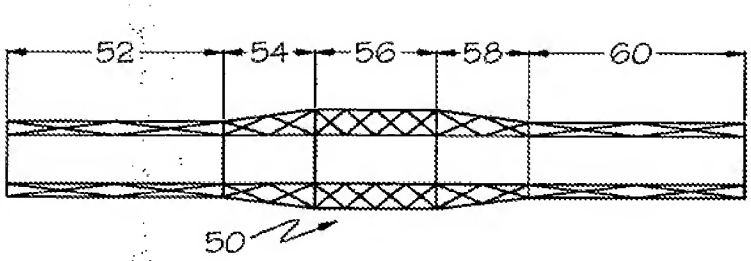

FIG. 3

Figure 3 depicts a tubing segment 50 for a balloon parison with varied orientation over the length having minimum regions 52 and 60, transition regions 54 and 58, and central region 56. (Spec. 7:28 – 8:4).

4. Figure 7 of Pepin is reproduced below:

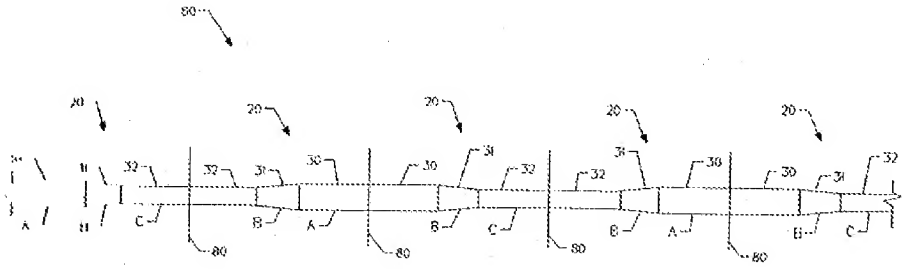

FIG. 7

Figure 7 depicts a tubular member 60 with varying dimensional characteristics with minimum regions 32, transition regions 31, and central region 30. (*See* Col. 7, ll. 43-59).

5. Pepin states: "[b]y using the novel process of the present invention, dimensionally variable tubular members may be formed to desired specifications to meet required operational and performance characteristics without sacrificing the structural integrity of the tubular member." (Col. 7, ll. 15-19).

PRINCIPLES OF LAW

"Anticipation requires that every limitation of the claim in issue be disclosed, either expressly or under principles of inherency, in a single prior art reference." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1255-56 (Fed. Cir. 1989).

ANALYSIS

Appellants have grouped certain claims subject to each of the two grounds of rejection separately. However, Appellants rely on similar arguments for claims 23-25. Accordingly, we confine our discussion to appealed claims 23, 24, 43, and 44, which contain claim limitations representative of the arguments made by Appellants pursuant to 37 C.F.R. § 41.37(c)(1)(vii).[2]

Claim 23

Appellants do not dispute the Examiner's finding that the changes in drawing rate disclosed in Pepin inherently result in different orientations for the resulting polymeric material. (*See* App. Br. 5). Rather, Appellants contend that although a balloon parison starts out as an extruded tube, once the different regions are slated the tubing segment is a parison that is qualitatively differentiated from tubing extrusions intended for other purposes such as catheter shaft or tip sections. (App. Br. 6-7). Appellants argue that the claim does not read on extruded tubing with different orientation along its length. (App. Br. 7). Appellants contend that Pepin

[2] Only those arguments actually made by Appellants have been considered in this decision. Arguments which Appellants could have made but chose not to make have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2007).

does not disclose forming balloon parisons, arguing that Pepin's Figure 7 shows the formation of soft catheter tips. (App. Br. 8-9, FF 4). Appellants admit that Pepin discloses slated portions, but argue that the slated portions disclosed by Pepin do not satisfy the recitations of claim 23, because the slated portions have "nothing to do with balloons or balloon segments." (App. Br. 9).

Appellants have not directed our attention to any persuasive evidence that the recited method of forming a slated parison is different than Pepin's method. Specifically, Appellants' claims do not place any particular limitations on the extent of longitudinal orientation or variation of wall thicknesses in forming the cone and waist slated portions of the parison as compared to the longitudinal orientation in the method of Pepin. Thus, Appellants have not demonstrated that referring to the extruded tube as a "parison" having "cone and waist slated portions" necessarily imparts any patentable distinction between the method of the present claims and the method of forming the slated extruded tubes of Pepin. Moreover, regarding Figure 7 of Pepin, Appellants have not presented any persuasive evidence demonstrating any qualitative structural differences between the extruded tube with varying longitudinal orientation produced by Pepin's method as depicted in Figure 7 and the balloon parison produced by Appellants' method as depicted in Appellants' Figure 3. (*See* FF 3 and 4).

Regarding claim 24, Appellants contend that Pepin does not disclose the extrusion/slating relationship recited in the claim. (App. Br. 9-10). However, Appellants have failed to point out with any specificity why the Examiner's rationale regarding the varying the drawing/pulling rate is in error. (Ans. 4). Therefore, we are not persuaded by Appellants' argument.

Claim 43

Appellants do not dispute that Pepin shows a process for extruding polymeric tubing where the drawing rate is altered to provide at least two regions having different elongation at yield properties. (App. Br. 11-12). Rather, Appellants contend that Pepin does not teach selecting the drawing rate based on the elongation at yield properties. (App. Br. 12). Appellants argue teach selecting the drawing rate based on the elongation at yield properties is a choice criterion and Pepin does not show that there was a desire to use a known parameter as a proxy for the elongation property. (App. Br. 12-13). Appellants additionally contend that different elongation properties, if produced, would be a result of the alteration not the basis of the alteration. (Reply Brief filed September 16, 2008, 5).

We agree with the Examiner, that Pepin describes a choice to change dimensions by adjusting the drawing/pulling rates, which changes the elongation at yield properties in the same locations. (Ans. 10-11). Claim 43 does not recite any particular variation of elongation at yield properties. In addition, Appellants do not specifically address the Examiner's position that Pepin discloses that varying the drawing rate effects the dimensional characteristics, which in turn affects other operational and performance characteristics inclusive of elongation properties. (Ans. 4-5 and 10-11; FF 5). Therefore, Appellants' arguments are not persuasive.

Claim 44

Regarding claim 44, we agree with Appellants that Pepin does not disclose the specific variation in elongation at yield recited in the claim. (App. Br. 13). Accordingly we cannot sustain the Examiner's rejection of claims 44 and 45 under 35 U.S.C. §102(b).

CONCLUSION

Appellants have failed to demonstrate that the Examiner reversibly erred in finding that Pepin discloses a method of making a parison as recited in claim 23.

Appellants have failed to demonstrate that the Examiner reversibly erred in finding that Pepsin discloses the method of forming the polymeric tubing segment recited in claim 43.

Appellants have demonstrated that the Examiner reversibly erred in finding that the difference in elongation at yield value recited in claim 44 is inherent to Pepin's method.

ORDER

We affirm the Examiner's decision rejecting claims 23-25 and 43 under 35 U.S.C. § 102(b) as being anticipated by Pepin as evidenced by Chen.

We reverse the Examiner's decision rejecting claims 44 and 45 under 35 U.S.C. § 102(b) as being anticipated by Pepin as evidenced by Chen

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. §1.136(a)(1)(v).

AFFIRMED-IN-PART

tc
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